REMARKS

Claims 1, 4-8, 18, and 21-25 are pending in the application. The amendments to the claims are made to further clarify the presently claimed invention. Newly added claims 21-25 find bases at *inter alia*, page 3 in the specification. No new matter has been inserted into the application. Furthermore, since the claims are directed to either clarifying the claim language or inserting the limitations of dependent claims into the independent claims, it is believed that no new issue is raised requiring further search or consideration. Therefore, entry of the amendments to the claims is respectively requested.

Information Disclosure Statement

In reference to the Examiner's comments in the Office action of November 21, 2005, Applicants submit herewith a revised IDS that was originally submitted on August 5, 2003, which now includes the titles of the various references. The Examiner is respectfully requested to review, initial and return a copy to the undersigned.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-20 have been rejected for allegedly not being enabled by the description. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants note that the presently claimed invention is directed to a method of reducing glomerulosclerosis of a subject, comprising delivering to the kidney of the subject in need thereof a therapeutically effective amount of a gene encoding IL-10. The invention is also directed to a method of reducing progression of proteinuria of a subject suffering from a renal

disorder comprising delivering to the kidney of the subject in need thereof a therapeutically effective amount of a gene encoding IL-10.

The Examiner has stated numerous reasons why he believes that the presently claimed invention is not enabled by the specification. Some of these reasons include allegation that the FGS/Kist mouse is not an acceptable model for kidney disease. The Examiner also refers to the difficulty in the art of providing or delivering genes into cells of interest, as well as the mobilization of the cells to the target area, and further the function of the proteins that are expressed at the site of interest. The Examiner further goes on to argue that gene therapy is a largely unpredictable art, and therefore more or better evidence should be disclosed to provide enabling disclosure for the claimed invention. The Examiner further cites Choi et al. (2003 Gene Therapy, 10:559-68), which is Applicants' own publication published after the effective filing date of the present application to support the Examiner's view that the claimed invention is not enabled by the instant specification.

In response, Applicants note that the FGS/Kist mouse model shows all of the symptoms of a mouse that is destined to develop nephritis. Indeed, as shown in Example 15 in the specification, untreated FGS/Kist mouse strain does develop glomerulosclerosis. However, when this mouse model is treated with a viral vector comprising human IL-10 gene at the onset of glomerular damage, which begins at six weeks from birth, and the mice were sacrificed and examined at the 10 week mark, their glomerular index was dramatically lowered such that in the female the glomerulosclerosis index was negligible, as compared with the naïve control which showed a glomerulosclerosis index of 0.06 +/- 0.06. Therefore, it is clear that Applicants have provided data that show reduced glomerulosclerosis in an animal that is scientifically designated and named as such for developing glomerulosclerosis if left untreated. Further, when a virus

comprising human IL-10 is injected into the mouse at the onset of full-blown nephritis, improved results were seen where there was reduced glomerulosclerosis as well as reduced proteinuria. Certainly, such data are persuasive of at least the effects of the IL-10 gene in the changed physiological condition of these diseased mice.

In the present situation, actual reduction or elimination of disease symptoms was observed in the FGS/Kist mice. Actual glomerulosclerosis index was lowered. Proteinuria was observed to be reduced. These are concrete results of reduction in symptoms of a disease that is being treated, and not mere descriptions of mechanisms of how a disease may be manifest. In view of the clear data presented in the present specification, it is unclear to the Applicants as to what further showing or evidence is required in order to pass the instant claims to issue. Applicants once again assert that the presently claimed invention is fully enabled by the present specification.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR §§ 1.16 and 1.17 that are not covered, in whole or in part, by a credit card payment enclosed herewith and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

JHK Law

Dated: December 14, 2006

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